Policy & Procedure (P& P)

Policy Title :		
Screening of Donated Blood		
Department	**Index No.**	**Scope**
Laboratory & Blood Bank	LAB-074	All Blood Bank and Lab Staff
Issue Date	**Revision NO**	**Effective Date**
1432/06/04	4	1440/07/23
Review Due Date	**Related Standard NO.**	**Page Number#**
1442/07/23	CBAHI (LB.51)	4

01. Policy:

01.1. All blood units are screened to the Transfusion Transmitted Disease markers according to the AABB policy by ELISA or chemiluminescence assay AND Nucleic Acid Amplification Test: NAT tests.

02. Definition :

N/A

03. Purpose :

03.1. To provide safe blood free from Transfusion Transmissible Disease (TTD) according to the AABB policy.

04. Procedure :

- The blood bank technician, every morning, writes the serial numbers of the Blood bank serology report with signature and stamp then sends the samples to the Serology department where serological tests are performed by chemiluminescence assay (Architect) and Nucleic Acid Technique "NAT".
- The serology department performs the following tests to each donated unit:
  1. HBs Ag.
  2. Anti-HBc
  3. Anti-HBs Ab for all Anti-HBc positive samples
  4. Anti-HCV

5. Anti-HTLV I, II
6. Serological test for syphilis (RPR).
7. HIV I/ II combo (anti HIV I/ II antibodies and P24 Antigene)
8. HIV RNA
9. HBV DNA
10. HCV RNA
11. Malaria thick film stained by Giemsa stain.

Note:

1. Donor's sample is collected in 6 ml plain tube to perform the chemiluminescence assay.
2. Donor's sample is collected in 7ml EDTA tube to perform NAT Test for (HIV/HBV/HCV) for all blood donors.
3. All blood component units are stored in a separate secured proper storage places: a separate refrigerator labeled UNSCREENED BLOOD until all TTD test results released then the bags will be shifted to another refrigerator for SCREENED BLOOD or discarded.
4. **Interpretation of Tests:**
   - 4.1. Results are received from serology department as reactive (+) or non-reactive (NR) for the tests.
   - 4.2. Two blood bank staff Compare the donor's results by both chemiluminescence assay and NAT tests.
   - 4.3. Blood is discarded if either chemiluminescence assay or NAT tests is positive.
   - 4.4. All blood component units with positive screen TTD test results are repeated in duplicate one sample from blood unit and another sample from the test tube before the release of the whole batch of donation, to solve any problems about labeling.
   - 4.5. All repeat TTD positive screen test result must be confirmed by NEUTRALISATION for HBV or Western Blot for (HIV I, II and HTLV I, II) and RIBA for HCV and PCR for NAT tests which was approved by FDA or CE with blood sample from the donor.
   - 4.6. All units positive for HBs Ag, HCV Ab, HIV I, II Ab, HIV P24, HTLV I, II, Syphilis, HIV RNA, HCV RNA, HBV RNA or malaria are discarded.
   - 4.7. Anti HBs test should be performed to all anti-HBc positive samples:

- if antiHBs result is negative discard blood units
- if anti-HBs result is positive and the antibody titer is above 1000 mIUnit keep the unit and use it due to presence of Natural Immunity in this donor for HBV regarding that DNA-NAT test is negative.
- if anti-HBs result is positive and the antibody titer is between 100 mIUnit and 1000 mIUnit keep the units of platelets and discard the units of Fresh Frozen Plasma FFP and keep the unit of PRBCs in quarantine and use it only in emergencies.

4.8. Donors with positive TTD tests are referred to the Infection Control Department for follow up.

4.9. All blood donors with positive screening or confirmatory results for HIV I, II and HTLV I, II, HBV and HCV are DEFERRED PERMANENTLY.

4.10. All blood donors with positive MALARIA test are DEFERRED FOR THREE YEARS from the date of treatment and cessation of symptoms.

4.11. All blood donors with SYPHILIS test or history of Gonorrhea are DEFERRED FOR ONE YEAR from the date of treatment and cessation of symptoms.

4.12. All blood component units with negative screen TTD test results are rechecked by TWO QUALIFIED PERSONS from blood bank (BB supervisor or technician and physician) and should sign the result before labeling.

4.13. All blood component units with rechecked negative screen TTD test results are labeled with a special label sticker with the mention of NON-REACTIVE for all TTD then are stored in separate secured proper storage refrigerator labeled SCREENED BLOOD after release of all results to be ready for transfusion.

4.14. All blood component unit's storage places (Fridges, Freezers and platelet incubators) are labeled: SCREENED BLOOD for the screened Blood and UNSCREENED BLOOD for unscreened blood

4.15. On release of any Non-Reactive Blood Component units the technician will check again for TTD test results reports and check if it is non-reactive before release.

05. Responsibilities :

05.1. All Blood Bank Staff, Serology Staff and Hematology Staff of Al-Qunfudah General Hospital

06. Equipment & Forms

06.1. Blood Bank Report Form for serology results.

06.2. Blood Bank Report Form for malaria parasite.

07. Attachment :

N/A

08. Reference

08.1. The Technical Manual of the American Association of Blood Banks.

Preparation , Reviewing & Approval Box

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وزارة الصحة Ministry of Health
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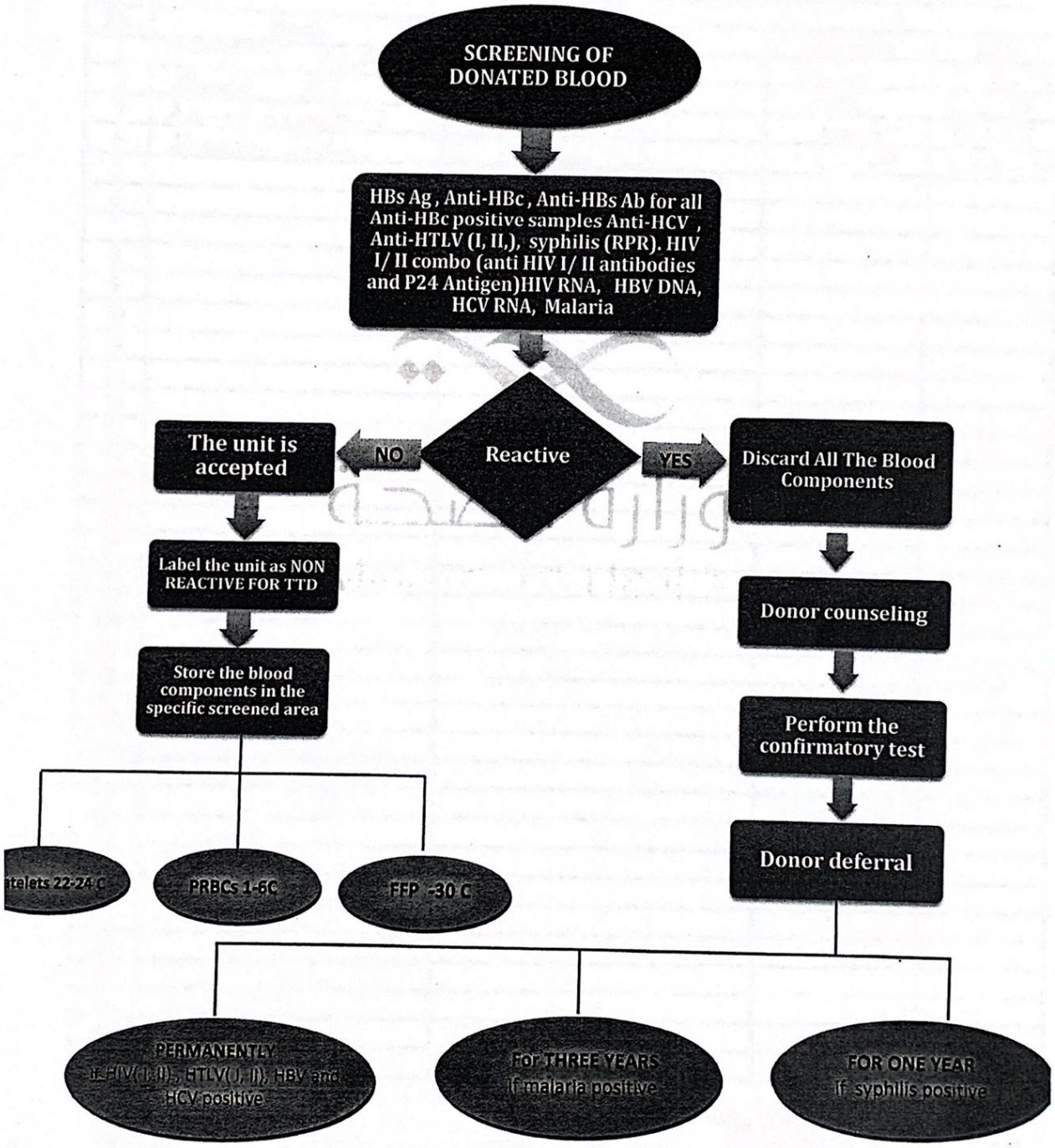
إدارة الجودة الشاملة
TQM

وزارة الصحة
Ministry of Health
مستشفى القنفذة العام
Al Qunfudah General Hospital

Appendix A: (Donor screening flow chart) :



Ministry of Health

AL QUNFUDAH GENERAL HOSPITAL

Department: Blood Bank

Signature Sheet For Policy And Procedure

Policy And Procedure Title	Screening of Donated Blood	Policy And Procedure No.	LAB-074

No.	Name	Title	Signature	Date
1	Mohammed Alshaybn	Lab Tech		12-6-19
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3	Ahmad Algahtani	Lab Tech		12/6/19
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